



ECSi

"Your Regulatory Compliance Expert"

May 21, 2020

Mr. Dan Coleman
Facilities Department
ABBOTT VASCULAR
26531 Ynez Road
Temecula, California 92591

Subject: **RESULTS OF ANNUAL ETHYLENE OXIDE SOURCE TESTING AND LEAK TESTING PERFORMED AT ABBOTT VASCULAR IN TEMECULA, CALIFORNIA**

Dear Mr. Coleman:

Please find attached a presentation of the results of the ethylene oxide source testing and leak testing performed at your facility by ECSi, on Thursday, May 21, 2020. These test results are to be kept with all records pertaining to SCAQMD-required testing of the EtO gas-sterilization system, and are to be made available upon request by the SCAQMD. A copy of all raw test data, complete with sample chromatograms and calibration data, will be maintained in our files, and will be made available upon request.

The test results indicate that you continue to operate your EtO sterilization and emission-control system (SCAQMD Permit Numbers F83295 and F83299) in compliance with SCAQMD Rule 1405. I will follow up with you in approximately five months to let you know when your next semi-annual leak test is due, and in approximately eleven months to let you know when your next annual source test/leak test is due.

The annual ethylene oxide emissions reported in Table 2 can be used for your facility's annual SCAQMD emissions report. If you have any questions or comments regarding this submittal, please contact me at (949)400-9145. We thank you for the opportunity to serve your needs.

Respectfully Submitted:

Daniel P. Kremer
ECSi

TABLE 1
ETHYLENE OXIDE CONTROL EFFICIENCY
OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE (ABATOR #2 - F83299)
OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
IN TEMECULA, CALIFORNIA
ON MAY 21, 2020

<u>CYCLE PHASE</u>	<u>INJECTION TIME</u>	<u>INLET ETO CONC. (PPM)(1)</u>	<u>OUTLET ETO CONC. (PPM)(2)</u>	<u>ETO CONTROL EFFICIENCY</u>
Exhaust(3)	1353	2010	0.01	99.9995
Exhaust	1355	37.2	0.01	99.9731
Exhaust	1357	1670	0.75	99.9551
Exhaust	1359	1780	0.69	99.9612
Exhaust	1401	417	0.01	99.9976
Exhaust	1403	1260	0.01	99.9992
Exhaust	1405	249	0.01	99.9960
Exhaust	1407	1110	0.01	99.9991
Exhaust	1409	3820	0.01	99.9997
Exhaust	1411	3060	0.01	99.9997
Exhaust	1413	3310	0.01	99.9997
Exhaust	1415	1690	0.01	99.9994
Exhaust	1417	1170	0.01	99.9991
Exhaust	1419	641	0.01	99.9984
Exhaust	1421	<u>14.3</u>	<u>0.01</u>	<u>99.9301</u>
TIME-WEIGHTED AVERAGE:		1483	0.1047	99.9871
Aeration(3)	1423	1850	0.01	99.9995
Aeration	1425	768	0.01	99.9987
Aeration	1427	<u>33.7</u>	<u>0.01</u>	<u>99.9703</u>
TIME-WEIGHTED AVERAGE:		400.9	0.0100	99.9845
TIME-WEIGHTED AVERAGE CONTROL EFFICIENCY:				99.9868
SCAQMD REQUIRED CONTROL EFFICIENCY:				99.0

Notes:

- (1) - PPM = parts per million by volume
- (2) - 0.01 ppm is the quantification limit for the detector used at the outlet.
- (3) - The exhaust phase started at 13:51, ended at 14:22.
- (4) - The aeration phase started at 14:22, the first chamber evacuation was tested.

TABLE 2
ETHYLENE OXIDE MASS EMISSIONS
FROM A GAS STERILIZATION AND EMISSION CONTROL SYSTEM (F83299/F83295)
OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
IN TEMECULA, CALIFORNIA
ON MAY 21, 2020

<u>CYCLE PHASE</u>	<u>STACK FLOW(1)</u>	<u>OUTLET ETO MASS FLOW(2)</u>	<u>MINUTES/ CYCLE</u>	<u>CYCLES/ YEAR</u>	<u>ANNUAL ETO MASS EMISSIONS(3)</u>
Exhaust	48.9 DSCFM	0.00000059 lbs/min	31	60	0.0011 lbs/year
Aeration	48.9 DSCFM	0.00000006 lbs/min	6	60	0.00002 lbs/year
TOTAL ANNUAL ETO MASS EMISSIONS					0.0011 lbs/year

Notes:

(1) - DSCFM = Dry Standard Cubic Feet per Minute

(2) - lbs/min = pounds per minute

(3) - lbs/year = pounds per year

TABLE 3
ETHYLENE OXIDE LEAK TESTING
OF A GAS STERILIZATION SYSTEM (F83295)
OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
IN TEMECULA, CALIFORNIA
ON MAY 21, 2020

<u>COMPONENT GROUP TESTED</u>	<u>LEAKING COMPONENTS FOUND</u>	<u>CONCENTRATION</u>
Gas Cartridge / Injector	None	<1.0 ppm (1)
Sterilizer Inlet / Inbleed Valve	None	<1.0 ppm
Door Seal	None	<1.0 ppm
Sterilizer Outlet / Chamber Drain	None	<1.0 ppm
Venturi System / Filter	None	<1.0 ppm
Emission Control Device Inlet	None	<1.0 ppm

Notes:

(1) - PPM = parts per million by volume

Abator #2 (F83299) - Sterilizer #2 (F83295)

<u>DeltaP</u>	<u>SqRtDeltaP</u>	<u>Temp (F)</u>	<u>ppm EtO</u>			
					stack ID =	3 in.
					stack area =	0.049 sq. in.
					press =	28.80 in. Hg
					Tstd =	528 deg R
					Pstd =	29.92 in Hg
					Cp =	0.99
					Kp =	85.49
0.11	0.3317	333	0.01			
0.11	0.3317	337	0.01			
0.11	0.3317	341	0.75			
0.11	0.3317	350	0.69			
0.11	0.3317	365	0.01		Velocity =	28.49 ft/sec
0.11	0.3317	382	0.01		Flow =	48.9 dscfm
0.11	0.3317	399	0.01			
0.11	0.3317	416	0.01		MWeto =	44.05
0.11	0.3317	424	0.01		MolVol =	385.32
0.11	0.3317	432	0.01		ppmv/ft3 =	1000000
0.11	0.3317	433	0.01			
0.11	0.3317	432	0.01			
0.11	0.3317	436	0.01		EtO Mass Flow (Exh) =	0.00000059 lbs/min
0.11	0.3317	417	0.01			
0.11	0.3317	399	0.01		min/cycle =	31
					cycles/year =	60
					EtO Emissions (Exh) =	0.0011 lbs/year
					EtO Mass Flow (Aer) =	0.00000006 lbs/min
					min/cycle =	6
					cycles/year =	60
Average =						
0.1100	0.3317	386			EtO Emissions (Aer) =	0.00002 lbs/year
	=	846	degR		Total EtO Emissions =	0.0011 lbs/year
					Average Exhaust Concentration =	0.1047
					Average Aeration Concentration =	0.0100